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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,320	08/07/2001	Mark Huang	P893 US	3586
28390	7590	11/01/2004	EXAMINER	
MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,320

Applicant(s)

HUANG, MARK

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 6, 8, 9, 10, 12, 14 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,066,156 to Yan.

Regarding claims 1, 2, 9, 10, 12, 14, 16 and 27, Yan discloses a balloon stent assembly comprising a balloon comprising an outer layer portion (adhesive 16), a stent (stent 18) disposed on the balloon covering at least 90 percent of the outer layer portion. Yan discloses that the outer layer portion flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature and retains the stent on the balloon during intravascular movement (Column 4 lines 3-15 and Column 7 lines 32-35).

Regarding claim 3, Yan discloses an inner layer (balloon 14).

Regarding claims 6 and 8, Yan discloses that the outer layer comprises a functionalized material that is not tacky below the predetermined temperature (Column 5 lines 45-56 and Column 7 lines 28-34).

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/33422 to Stoltze et al.

Regarding claims 1 and 2, Stoltze discloses a balloon stent assembly system comprising: a balloon (FIG. 5) including an outer layer portion; and a stent (stent 3) disposed on the balloon, the stent covering at least 55 percent of the outer layer portion

Art Unit: 3731

(FIG. 5); wherein the outer layer portion flows into gaps formed in the stent when the balloon stent assembly is heated (Page 14 line 14-Page 15 line 5) to a predetermined temperature, and retains the stent on the balloon during intravascular movement.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-10, 12, 14 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/33422 to Stoltze et al in view of U.S. Patent No. 5,797,877 to Hamilton et al.

Stoltze discloses the claimed invention except for the balloon being formed of an inner layer and an outer layer. Hamilton teaches that balloons may be made of two layers as opposed to one layer in order to obtain a balloon with a softer feel; superior abrasion and puncture resistance; lower required insertion, placement and withdrawal forces; and lower balloon resistance to inflation and deflation pressure (Column 6 line 58-Column 7 line 15). Hamilton also teaches that functionalized materials may be added to the balloon layers in order to increase the balloons adhesive properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Stoltze with an additional balloon layer in order to obtain a balloon with a softer feel; superior abrasion and puncture resistance; lower required insertion, placement and withdrawal forces; and lower balloon resistance to inflation and deflation pressure.

Regarding claims 6, 7 and 8, Stoltze discloses that the outer layer comprises a functionalized material selected from a group consisting of: polyethylene, ethylene-vinyl-acetate, acrylate, Bynel.RTM., and Plexar.RTM.(Page 16 lines 13-31).

Regarding claims 12 and 14, Stoltze discloses that the stent covers at least 90% of the outer layer portion (FIG. 5).

Regarding claims 22, 24 and 25, Stoltze discloses a method of retaining a stent on a balloon comprising: mounting the stent onto the balloon, the stent including gaps, the stent covering at least 55 percent of the balloon; sheathing the mounted stent and balloon (FIG. 7); heating the balloon; and flowing an outer layer of the balloon into the gaps formed in the stent while an inner layer of the balloon does not flow (Page 14 line 14-Page 15 line 5).

Regarding claims 16 and 23, Stoltze discloses that heating the balloon comprises elevating the balloon temperature to a temperature of about 50 to 70 degrees Celsius (Page 14 lines 19-23).

Regarding claim 26, Stoltze discloses pressurizing the balloon (page 14 lines 23-28).

6. Claims 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/33422 to Stoltze et al. in view of Hamilton et al. '877 as applied to claims 3-10, 12, 14 and 16-27 above, and further in view of U.S. Patent No. 5,807,327 to Green et al.

Stoltze, as modified, discloses the claimed invention except for the stent retention force. Green teaches that the use of the material urethane will create a suitable stent retention force (Column 8 lines 55-60). It would have been obvious to one having ordinary skill in the art to provide the device of Stoltze, as modified, with the stent retention force of Green in order to prevent slippage of the stent from the balloon prematurely.

Response to Arguments

7. Applicant's arguments filed June 21, 2004 have been fully considered but they are not persuasive.

Regarding Yan '076, the arguments appear to be based on a method of mounting a stent on a balloon. Claims 1-21 and 27 are apparatus claims, not method claims. The *structural* limitations, as claimed, are met by Yan' 076. The adhesive layer is part of the balloon since it is coated onto the balloon and is not separated from the balloon after its application. Applicant argues that Yan's outer layer (the adhesive) is not "non-tacky". However Yan '096 discloses that the adhesive may be "non-tacky" above or below a transition temperature (Column 7 lines 23-34). Yan has clearly indicated that the adhesive may be modified to be "non-tacky" below the transition temperature. Therefore, the rejection over Yan '076 is proper.

Regarding Stoltze, applicant argues that Stoltze does not disclose an inner layer and an outer layer. However applicant only claims an inner layer portion and an outer layer portion in claims 1 and 2. A single layer can have an inner and an outer *portion*. Therefore, the rejection over Stoltze is proper.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

Art Unit: 3731

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jrb
jrb

Jessica R Baxter
Examiner
Art Unit 3731

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER